and EF at one year between the two groups. The results are expressed as mean ± SD. Results: Of the 988 patients randomised, 972 (98.4%) were alive at one year. In the surviving patients 764 (79%) had available WMSI calculations and 515 (53%) had EF measured at one year. The WMSI in the CABG group (n=383) was 1.3 ± 0.4, compared with 1.2 ± 0.4 in PCI group (n=381), (P=0.48, t-test). The EF in the CABG group (n=245) was 54.8 ± 9.6, compared with 55.3 ± 9.3 in PCI group (n=270), difference = 0.5, 95% CI -1.1 to 2.1, (P=0.55, t-test). Compared with the pre procedural values both groups showed a similar change in WMSI and EF. The WMSI was greater at 12 months: CABG group 1.19 versus 1.27, (mean difference 0.08, 95% CI 0.04 to 0.11, p<0.001, Wilcoxon signed rank test), PCI group 1.19 versus 1.26 (mean difference 0.07, 95% CI 0.03 to 0.10, p=0.001). EF was lower in both groups: CABG group 57.5 versus 54.9, (mean difference –2.7, 95% CI –4.0 to –1.4, p<0.001, Wilcoxon signed rank test), in the PCI group 56.7 versus 54.9 (mean difference –1.9, 95% CI –2.9 to –0.8, p=0.001).
Conclusions: No difference was observed in the Stent or Surgery study at one year, in LV function in patients treated with PCI or CABG. At one year there has been a minor decline in global and regional function which may be attributable to the occurrence of factors which affect the cardiac function.

1076-185 Final Angiographic and Clinical Results of the Latin America Small Vessel Randomized Study (LASMAL Trial)

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Background: There were a conflictive data about the role of stents preventing restenosis in small coronary arteries.
Methods: Between March to December 2001, 246 patients with severe stenosis in small native coronary artery (≤ 2.9 mm) and clinical indication of myocardial revascularization were randomized in 15 centers of Latinamerica, 124 were randomized to stent and 122 to PTCA . In order to validate the reference diameter (RD) of the vessel , a comparative analysis between quantitative coronary angiography (QCA) and Intravascular Ultrasound was perform. The end point of the study was to compare angiographic binary restenosis, minimal luminal diameter (MLD), net gain, target vessel revascularization (TVR) and freedom from major adverse cardiovascular events (MACE) at six months of follow up, between both revascularization strategies.
Results: Both groups had similar clinical demographics and angiographic characteristics.
After randomization in the PTCA group, 18% crossed over to stents during the initial procedure. Intravascular Ultrasound showed a RD in stent and PTCA of 2.8 and 2.76 mm respectively (ns). At 30 days patients in stent arm had less incidence of MACE than those included in PTCA (2.4% vs 9.8% respectively p=0.045) Six months follow up angiogram was obtained in 91% of patients.

Six months QCA and Clinical Data	PTCA (122)	Stent (124)	p
RD (mm)	2.47 ± 0.23	2.5 ± 0.20	0.246
MLD Post (mm)	2.1 ± 0.30	2.3 ± 0.25	0.0002
MLD Follow up(mm)	1.53 ± 0.67	1.76 ± 0.67	0.013
Net Gain (mm)	0.81 ± 0.69	1.11 ± 0.68	0.002
Restenosis (%)	29	19	0.118
TVR (%)	18	14.5	0.568
MACE (%)	27	16.9	0.078

Conclusions: An initial strategy with stents at long term follow up achieved better MLD and net gain than those initially treated with PTCA. Angiographic restenosis and MACE showed a trend to be low with stent therapy.

1076-186 Results of the PIXEL Study: Randomized Multicenter Trial Comparing Direct and Conventional Predilation Stenting in Small Vessels

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Background: Coronary stenting has been established the preferred form of percutaneous revascularization in vessels ≥ 3.0 mm in diameter, accounting for more than 80% of the procedures, half of those performed without prior balloon pre-dilation. Trials trying to establish the role of stenting in small vessels have offered contradictory results and feasibility and safety of direct stenting in < 3.0 mm vessels has not been tested.
Objective and design of the study: The primary objective of the study is to demonstrate the medium term efficacy of a no pre-dilatation strategy for elective stent implantation in native coronary arteries ≥ 2.2mm and ≤2.7 mm in diameter by on line QCA. The study is a prospective, randomized trial of 350 patients recruited by 28 hospitals from Europe, South America, India and New Zealand. The stent used was specially designed for small vessels (Pixel stent).The patients were centrally randomized 1:1 to stent implantation with and without pre-dilation. Enrollment started in June 2001 and was completed in August 2002. Mean patient age was 64 years; 176 patients were randomized to pre-dilation and 174 to direct stenting.
Endpoints: The primary endpoint is procedure success in the no pre-dilation group : attainment of final result of <30% in stent residual stenosis in the absence of MACE at 30 days. Secondary endpoints include : Acute success, procedural and fluoro time; Angiographic restenosis , target site revascularization and target vessel failure at 6 months; MACE at 6 months. Clinical and angiographic data post procedure and at follow up will be evaluated by independent corelabs.
In conclusion: The results of the PIXEL study will help to determine the role of direct stenting in small vessels . This knowledge might prove to be of great interest in the forthcoming era of drug eluting stents.

1076-187 Timing and Risk Factors for Enzymatic Myocardial Infarctions in Patients Undergoing Percutaneous Intervention: Insights From TARGET

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BACKGROUND: Glycoprotein IIb/IIIa receptor inhibitors (GPI) reduce peri-procedural ischemic events in pts undergoing PCI. The optimal timing of blood draw(s) to detect CK-MB elevations after PCI is not well established, and less is known about their clinical predictors. METHODS: In the TARGET trial, 4809 patients undergoing PCI were randomized to abciximab vs tirofiban. CK-MB values were determined every 6 hrs. Timing of MB elevations, correlation with symptoms, and its predictors were evaluated from 4329 pts. RESULTS: Enzymatic infarcts (MI, single MB value >3X or a 50% rise above abnormal baseline) were seen in 5.9% of pts, of whom 93.9% were reportedly asymptomatic. Only 1.0% of pts had Q-wave infarctions after PCI, of whom 1/4 had peri-PCI symptoms. In contrast, 67% of pts with reported symptoms after PCI had enzymatic or Q-wave infarcts. Table shows detection rates of MI at each time point. In a logistic regression model, acute coronary syndrome (ACS), heparin use, and increasing age, but not diabetes, were independent predictors of peri-PCI MI. Pre-PCI clopidogrel use was an independent predictor for lower rates of MI (OR=0.57, CL [0.38-0.85]). CONCLUSIONS: In pts undergoing PCI, using GPI and contemporary stents, at least 3 blood samples within 24 hours are required for optimal detection of most MI. An 18-hr sample has the best detection rate as a single time point. While ACS is associated with high risk of MI, pre-PCI clopidogrel therapy may have a significant cardioprotective effect in limiting CK-MB rise.

Timing of MB elevations

	6-hr	12-hr	18-hr	24-hr	add'l sample
CK-MB>3X	5.8%	23.5%	47.0%	18.9%	4.8%

1076-188 Acute and Late Outcome After Directional Coronary Atherectomy Plus Stenting Versus Stenting Alone in True Bifurcation Lesions

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Background: The aim of this study was to assess acute and late outcome following treatment of true bifurcation lesions with Directional Coronary Atherectomy (DCA) plus stenting (DCA group) compared to stent alone (Stent group). **Methods and Results** 88 lesions in DCA group and 332 lesions in Stent group were analyzed. Baseline clinical and angiographic characteristics were well matched. Reference diameters in main branch (MB) and side branch (SB) were similar in two groups (3.1±0.5 vs. 3.0±0.5 and 2.4±0.5 vs. 2.4±0.5, p=NS). Bigger minimal lumen diameter (MLD) post-procedure and at follow-up was achieved in DCA group (table). Binary restenosis rate (MB 17% vs 34%, p=0.08 and SB 23.5% vs 41%, p=0.09) was lower in DCA group. There was no difference in rate of in-hospital major adverse cardiac events (MACE, i.e. death, non-Q and Q-wave myocardial infarction (MI), need of revascularization) between two groups (9% vs.9.6%; p=NS). At 20±18 months f-up MACE rate was lower in DCA group (13.6%vs.32.2%; p=0.02). In DCA group there were no deaths, MI or CABG and in Stent group 4 pts died, 7 had MI and 3 underwent CABG. Repeat PTCA rate was similar (13.6% vs. 24.8%, p=NS). **Conclusions:** DCA plus stenting in bifurcation lesions is not associated with an increased incidence of in-hospital MACE and results in improved clinical and angiographic outcome.

Variables	DCA	Stent	P value
MB MLD After procedure	3.19± 0.56	2.91± 0.57	0.006
MB MLD follow-up	2.0± 1.1	1.6± 0.8	0.05
MB Late loss	0.90± 1.2	1.2± 0.8	0.1
SB MLD After procedure	2.2± 0.5	2.01± 0.7	0.2
SB MLD follow-up	1.4± 0.7	1.2± 0.7	0.1
SB Late loss	0.6± 0.8	0.8± 0.7	0.4

1076-189 Clinical and Angiographic Effects of Directional Atherectomy in De Novo Coronary Artery Lesions Located at the Ostium of the Left Anterior Descending Artery

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Lesions located at the ostium of the left descending anterior artery (LAD) are considered an ideal target for directional atherectomy (DCA). Methods: we did a matched comparison of the immediate and mid term results of a series of 117 consecutive patients with

de-novo lesions located at the ostium of the LAD that underwent DCA before stenting (DCA+S) in 46 cases or that were treated with stenting alone (S) in 71 cases. Results: Technical success in DCA+S and S group was 95.6% and 95.7%, respectively, p=0.69. No differences were observed in in-hospital major adverse events (MACE, i.e. death, non-Q and Q-wave myocardial infarction, need of revascularization) (4.3 % for DCA+S and 4.2% for S respectively, p=n.s). Angiographic results are summarized in table. All patients had 6-months clinical follow-up: MACE rate was lower (even though not significatively) in DCA+S group than in S group, (20.0% vs. 35.5%, p=0.061). The angiographic follow-up was performed for 95 patients after 5.9±2.2 months and showed a significantly lower binary restenosis rate for DCA+S group in comparison to S group (10.8% vs. 33.3%, p=0.015). Conclusions: DCA before stenting in de-novo ostial LAD lesions is safe and is associated to a high rate of technical success. Follow-up data indicate that DCA+S in this setting provides a significantly larger MLD and lowers the incidence of restenosis if compared to stenting alone.

* = p<0.05 for comparisons between the two groups (independent samples t-test)

	Basal ref, mm, n=117	Basal MLD, mm, n=117	Acute Gain, mm, n=117	Late loss, mm, n=95	Loss index, n=95
DCA +S	3.4±0.5	1.1±0.5	2.4±0.8*	0.8±0.6	0.33±0.35*
S	3.4±0.4	1.2±0.5	2.1±0.7	1.0±0.7	0.59±0.42

1076-190 Unprotected Left Main Coronary Stenting: Predictors of Restenosis and Long-Term Follow-Up Results

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Background: Studies have reported excellent short and mid-term outcome of unprotected left main coronary artery (ULMCA) stenting with only 8-15% clinical restenosis rate. The predictors of restenosis after ULMCA stenting especially in high surgical risk patients have not been well established.

Methods: We present the complete follow-up results in 188 consecutive patients undergoing ULMCA stenting at our center from January 1998 to June 2002. Based on Parsonnet surgical risk score, patients were divided into high surgical risk (n=112) with a score >15 and low surgical risk (n=76) for <15 score.

Results: All patients underwent stenting, 85% after rotablation, and procedure was successful in all with one in-hospital death due to CVA. Mean age was 82±6 yrs, mean LVEF 31±14%, GP inhibitors use 76%, and elective IABP in 38%. Stenosis location: ostium in 25%, body/distal in 60%, and bifurcation in 15%. CK-MB elevation occurred in 21%, with >5x normal in 4%. Vascular complications occurred in 3%. All but one patients were discharged alive at a mean duration of 5±4 days. At a mean one-year follow-up there were 16 deaths: 8 cardiac (4 CHF, 2 MI, 1 arrhythmia, 1 stent thrombosis), 8 non-cardiac (4 CVA, 2 pneumonia, 1 hyperkaliemia, 1 neoplasm). A total of 28 patients (15%) required repeat intervention for recurrence of angina, heart failure, or positive non-invasive testing. One patient underwent CABG at follow-up. Protocol mandated angiography was done in 48 asymptomatic patients and none had >70% stenosis of LMCA. On multivariate analysis, independent predictors of restenosis were bifurcation lesion intervention (OR 4.2; 95% CI 2.2-6.8), diabetes (OR 2.4; 95% CI 1.8-3.2), and reference vessel diameter <3.75 mm (OR 3.2; 95% CI 2.2-4.3). Event free survival (MI, revascularization, or death) was 72% in high-risk versus 91% in low-risk patients (p=0.01).

Conclusion: The present analysis suggests that ULMCA stenting is a viable option with good long-term outcome, especially in patients with low risk for CABG. With introduction of coated stents, stenting of non-bifurcation ULMCA lesion may have equal outcome as CABG and can be recommended.

1076-191 Coronary Artery Bypass Graft or Stent to Treat Unprotected Left Main Coronary Artery Stenosis: Direct Comparison of Revascularization Strategies

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Background: Coronary artery bypass surgery (CABG) is the treatment of choice for patients with significant disease of the left main (LMCA) coronary artery. Recent data has confirmed both the safety and efficacy of percutaneous coronary revascularization (PCI) and stent implantation for LMCA disease in selected patients. To date no trial comparing CABG vs PCI has included patients with LMCA disease. We have evaluated in hospital and mid term outcomes in patients with significant (>50%) LMCA disease treated either by CABG or PCI.

Methods and Results: Between Jan 2000 and Dec 2001, 187 patients underwent elective revascularization for symptomatic LMCA disease: 115 CABG and 72 PCI. PCI and CABG patients were well matched in terms of diabetes (10% vs 14%, NS), previous MI (7.5% vs 8%, NS) and mean LVEF (57±14% vs 59±13%, N.S.). However, the PCI group had patients at higher risk, EuroScore was 4.9 vs 2.5, p=0,0001. There were more females (10.7 vs 6.4 %, p=0.002), older patients (74+9 vs 66+9, p=0.001), more obstrctive lung disease (19 vs 1.7%, p=0.0001) and more renal impairment (5.3% vs 1.6%, p=0.003) in PCI compared to CABG. In hospital events were : 3 deaths (1 PCI, 2 CABG, NS), 7 MI (4 PCI, 3 CABG, NS) 1 TLR (0 PCI, 1 CABG, NS) and 2 strokes (0 PCI, 2 CABG, NS).Total in-hospital event rate was equal in both groups (4.9% vs 4.9%, NS). At a mean follow up of 415± 215 days, there were 16 further deaths (10 PCI vs 6 CABG, p=0,06), only 9 were cardiac (5 PCI vs 4 CABG, NS), 2 MI (1 PCI vs 1 CABG, NS), 16 TLR (13 PCI vs 3 CABG, p=0.001). EuroScore was an univariate predictor of cardiac mortality: 5.5± 2.5 (cardiac death) vs 3.3 ± 2.1 (survivors), p=0.001. Kaplan-Meier analysis revealed cardiac death free survival at 1 year of 92±0.3% vs 94 ±0.3% (mean ± SEE), p=NS and MACE (death, MI, TLR) free survival of 66±0.5% vs 86±0.4%, log rank p=0.0001 for PCI vs CABG respectively.

Conclusions: The immediate and medium term survival following unprotected LMCA stenting was equivalent to CABG. The longer term outcome of PCI was limited by the need for TLR. Stenting offers an excellent alternative to CABG in patients with relative contraindications to surgery.

1076-192 Clinical Outcome After Multivessel Stenting in Diabetic Versus Nondiabetic Patients: Impact of Restenosis and Disease Progression

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Background: Diabetes Mellitus has a negative impact on outcome after percutaneous interventions (PCI). We examined our experience of multivessel PCI to determine the factors that limit the effectiveness of PCI in diabetic (DM) patients.

Methods and Results: Between Jan 2000 and Dec 2001 we performed multivessel PCI in 99 DM with 254 treated lesions versus 239 non-DM patients with 620 treated lesions. Both groups were well matched as regard clinical and lesions characteristics except that DM patients had more renal insufficiency (6.1% vs 0.8%). Number of diseased segments treated (2.8±0.9 vs 2.66±0.79) and stents implanted per patient (2.3±0.6 vs 2.47±0.72) were similar in the 2 groups. Angiographic and clinical results after a mean follow up of 433±275 days were:

	Diabetic	Non-diabetic	p value
QCA: Reference diameter (mm)	3.17±0.5	3.19±0.6	NS
Final MLD	3.19±0.68	3.21±0.6	NS
Final diameter stenosis (%)	1.26 ±8.1	2.1±7.6	NS
In-hospital Death/TVR	0	0	NS
In-hospital MI	7.1 %	3 %	NS
In-hospital MACE	7.1 %	3.3 %	NS
Follow-up Death	4 %	3 %	NS
Follow-up MI	8 %	3 %	NS
Follow-up TVR	29 %	16 %	0.03
MACE	38 %	23 %	0.04

The need for TVR was due to disease progression in 57% of DM patients and 26% in non DM patients p=0.02. The event-free survival was 65±0.5% vs 80±0.2 at 1 year and 55±0.6% vs 71±0.3 at 2 years (p=0.01) for DM and non DM respectively.

Conclusion: The medium and longer term success of multivessel PCI in diabetic patients is limited principally by the need for repeat revascularization which are performed not only for restenosis but also for disease progression. Consequently, even if drug eluting stent technology can eliminate restenosis, disease progression will continue to impact the clinical outcome of diabetic patients after PCI.

1076-193 Does Lesion Location Have an Impact on Long-Term Clinical Outcome After Unprotected Left Main Coronary Artery Stenting?

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Background: Unprotected left main (LM) coronary stenting is now an accepted alternative to coronary surgery with excellent immediate and long term outcomes in selected patients. However, the impact of the anatomical location of the target stenosis in the LM on clinical outcome is unknown. We set out to assess the impact of target lesion location on clinical outcome in unprotected LM stenting

Methods and Results: Between Jan 1994 and Aug 2002 we performed unprotected LM stenting on 214 consecutive patients. There were 167 (80%) male patients, mean age 74± 8 years, 24% diabetic, 12% renal insufficiency, mean LVEF 57± 14%. The anatomical location of the target lesion in the LM was: ostial 26%, mid-shaft 21% and distal bifurcation lesions 53%. Initial procedural success was 100%. The in-hospital MACE rate was 7.7% (7 deaths, 8 MI and 1 TLR). Follow up on 197 (98%) was completed for a mean of 23± 20 months. Total MACE rate during follow up was 31% (38 deaths, 5 MI and 35 TLR). There was a significant difference, by Kaplan Meier analysis, in MACE rates at 1 and 5 years comparing the distal (D) and non-distal (ND) (ostial and mid shaft) lesions: 61% and 39% for D and 78% and 62% for ND respectively, p<0.0001 . There was an increased mortality in the D group: 27% vs 14%, p=0.03 although cardiac mortality was not different 19% vs 11%, NS. There was no difference in the calculated Euroscore between patients with D and ND lesions: 4.9+2.5 vs 4.7+2 p=NS. There was also a significant difference in the TLR rates between the 2 groups: 27 vs 8, p=0.002 for D vs ND respectively.

Conclusion: Unprotected LM stenting can be performed with excellent immediate and long term outcomes in ostial and mid-shaft lesions. Stenting of unprotected distal LM lesions is associated with a significantly increased risk of death and TLR . The majority of the events was concentrated in the first 6 months following procedure suggesting an important role of in stent restenosis. This issue may be overcome in the near future by the use of drug eluting stents.